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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/625,558 | 07/24/2003 | Francesca Benedini | 026220-00038 | 8114 |

4372 7590 08/11/2005

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EXAMINER

SACKEY, EBENEZER O

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,558

Applicant(s)

BENEDINI ET AL.

Examiner

EBENEZER SACKY

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6 and 7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/031,412.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07/24/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Status of Claims

Claims 1-5 have been cancelled.

Claims 6 and 7 are pending.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed 07/24/03 is acknowledged and has been entered into the file accordingly. A signed copy of the 1449 is attached herewith.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soldato (U.S. Patent number 5,700,947) ('947').

Applicants claim 4-nitroxybutyl ester of 2-(S)-(6-methoxy-2-naphthyl)-propanoic acid having an enantiomeric excess of the (S) form higher than or equal to 97% or 98%.

Determination of the scope and content of the prior art (MPEP §2141.01)

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Soldato discloses a similar 4-nitroxybutyl ester of 2-(S)-(6-methoxy-2-naphthyl)-propanoic acid compound. See the entire reference, especially column 4, formula (V), lines 34-39 and column 7, lines 20-32.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the present claims and '947' is that the instant compounds are drawn to an (S)-enantiomer, whereas '947' discloses the racemate. However, it is generally known in the art that normally, one of the enantiomer of a racemate would possess a disproportionate amount of the desired biological activity. Thus, an enantiomer, stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties not possessed by the racemic mixture. *In re Anthony*, 162 USPQ 594, 596 (1969) and *In re Adamson*, 125 USPQ 233, 234 (1960).

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

Hence, the motivation to make the claimed compounds derives from the expectation that compounds structurally similar would possess similar activity (i.e., anti-inflammatory and/or analgesic activity).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare nitric esters of derivatives of propionic acid compounds as disclosed by Soldato, with a reasonable expectation of success absent a showing of unexpected results. Therefore, at the time of filing this application, one of ordinary skill in the art in possession of Soldato would have been in possession of the instant compounds absent a showing of unexpected results and/or properties.

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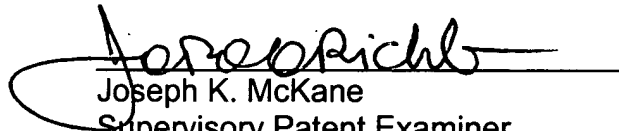
Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704.

The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS
August 6, 2005


Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1